DEPARTMENT OF HEALTH AND HUMAN SERVICES

Kathleen M. Murphy
Ludlow Technical Products
Two Ludlow Park Drive
Chicopee, MA 01022

3046 APR 12 2000 10:30

RE: Citizen Petition 00P-0442

Dear Ms. Murphy:

This responds to Ludlow Technical Product's petition, filed on January 28, 2000, requesting a temporary variance on behalf of health care providers from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898). Your petition asked that the Food and Drug Administration (FDA) extend the effective date of the performance standard to August 9, 2000, for health care providers to convert to compliant fetal scalp electrodes.

Your variance request is granted as it applies to your firm's fetal scalp electrodes in user facilities before May 9, 2000. Our decision is based on concerns about the potential for shortages of fetal scalp electrodes in some healthcare facilities, caused by implementation delays by your firm and other manufacturers. User facilities may continue to use their in-house stock of non-compliant FSE 1000 and FSE 2020 fetal scalp electrodes until August 9, 2000, at which time all health care providers using your fetal scalp electrodes and applicators must use products that comply with the performance standard.

We appreciate your concern that your firm will not be able to ship sufficient compliant electrodes *prior to* May 9, 2000, to assure a smooth transition. In turn, we understand that you will not ship any non-compliant electrodes *on or after* that date. User facilities may continue to use their existing non-compliant stock until they can receive new compliant fetal scalp electrodes.

As a condition of this action, please notify health care providers of this temporary variance. Prepare a notification letter to your existing customers notifying them of the specific provisions of the variance, their obligation to be in full compliance with the performance standard by August 9, 2000, and your anticipated delivery schedule for compliant fetal scalp electrodes. Your notification letter should issue to your customers within 15 days of your receipt of this letter, with a copy submitted to the Office of Compliance, HFZ-340, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, Maryland 20850.

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-26	Sheehan	4/7/00						

I trust that this response fully addresses your concerns. If additional information is required, please contact Sharon Murrain-Ellerbe in our Office of Compliance at (301) 594-4616.

Sincerely yours,

Linda S. Kahn
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

Draft: SEllerbe:03/21/00
Revised: ESCrumpler:4/5/00
Rev: PFTilton: 4/6/00
Rev: CEUldriks: 4/6/00

bcc:

HFA-224
HFA-305 (Docket No. 00P-0442)
HFR-NE200
HFZ-1
HFZ-3
HFZ-15 (JSheehan, MHanna, Files)
HFZ-141 (RWalchle)
HFZ-300
HFZ-305 (Precedent Correspondence)
HFZ-332 (SEllerbe, Files)
HFZ-340 (ESCrumpler)
HFZ-470 (CPollard, KDaws-Kopp)